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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,590	06/06/2000	Gary Karlin Michelson	101-0044-03000	7688
22882	7590	06/23/2006	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			BROWN, MICHAEL A	
			ART UNIT	PAPER NUMBER
			3764	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/497,590	Applicant(s) MICHELSON, GARY KARLIN	
	Examiner Michael Brown	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-115 and 121-194 is/are pending in the application.
- 4a) Of the above claim(s) 105-115, 121-148 and 188-194 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 149-168 and 170-187 is/are rejected.
- 7) ☒ Claim(s) 169 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3-31-06, 10/6/03 and 9/24/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 149-165, 167-168, 170-171, 173-180, 182-183 and 185-186 rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan in view of Ma.

Brantigan discloses in figures 1-11 an apparatus for use in human spinal surgery comprising a guard member 22, extension portions (the portions of 22 that extends outward near 23 but don't including 23), the extension have the same height (fig. 4), penetrating means 23, (that are teeth or prongs), a spinal implant 11, fusion promoting material (col. 1, lines 62-69 col. 2, lines 1-54), the penetrating means has a tapered end (fig. 4) the guard is a hollow sleeve (fig. 4), the distal end of the guard is contoured (fig. 4), the proximal end of the guard has an increased diameter (at the larger portions of 22 adjacent to 23), a bone removal device 21, the spinal implant is part bone and bone graft (col. 1 lines 62-69 – col. 2, lines 1-54), an implant driver 24 and the drill 21 has flutes (that allow for the removal of bone). However, Brantigan doesn't disclose the passage of the guide being a non-circular cross-section. Ma teaches in figure 17 a guide 44a having a passage (the inside of 44a) that is non-circular. It would have been

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obvious to one having ordinary skill in the art at the time that the invention was made that the passage of the guide disclosed by Brantigan could be fabricated with a non-circular cross-section as taught by Ma in order to be able to insert a non-circular or circular cutting tool into the guide. The guide could be also be used to insert a non-circular implant through the guide. The two extensions disclosed by Brantigan are capable of distancing apart two adjacent vertebral bodies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 166, 172, 181, 184 and 187 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Stednitz.

Stednitz teaches using a tap (tap threads) to form a threaded hole. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the tap as taught by Stednitz could be used to form a threaded hole in the vertebrae. It is a design choice to make the guard of a rectangular cross-section as taught by Ma. The end of the device away from 22 on the end opposite 23 is being interpreted as a cap. It is old and well known to use a press into compression a

substance into a container (a spinal implant). It is a matter of duplication to have a second distractor.

Allowable Subject Matter

Claim 169 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed March 31, 2006 have been fully considered but they are not persuasive. Applicant argues that it is improper to combine the teaching of Ma (forming a non-circular) guide with Brantigan because the guide lacks a non-circular cross-section. However, the examiner used Ma to provide a guide that the outer portion is non-circular. The examiner doesn't disagree that the inside provides a circular opening. Whether something circular can be inserted into the guide doesn't provide any novelty over the prior art. Applicant argues that the portions of the sleeve that the examiner is interpreting as extensions do not distance apart the adjacent vertebral bodies from at least in part within the disc space between the adjacent vertebrae bodies. However, the extensions disclosed by Brantigan are capable of distancing apart two adjacent vertebra bodies from at least in part within the disc space between the adjacent vertebrae bodies.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown
June 7, 2006

A handwritten signature in black ink, appearing to read "Michael A. Brown", with a long horizontal flourish extending to the right.

MICHAEL A. BROWN
PRIMARY EXAMINER